UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,613	06/27/2001	Shawn Shui-on Leung	655	4914

7590 12/15/2006

Albert Wai-Kit Chan
Law Offices of Albert Wai-Kit Chan, LLC
World Plaza Suite 604
141-07 20th Avenue
Whitestone, NY 11357

EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

TH

Office Action Summary	Application No.	Applicant(s)	
	09/892,613	LEUNG, SHAWN SHUI-ON	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/31/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-39 and 50 are cancelled.

Claims 40-45 have been amended.

2. Claims 40-49 are pending and under examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. This Office Action contains New Grounds of Rejections.

Rejections Withdrawn

5. The objection to the abstract of the disclosure is objected to because the abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4) is withdrawn in view of the newly submitted abstract filed 9/28/2006.

6. The objection to the disclosure for not being in sequence compliance because Figures 1-3 and 7-10 contain sequences that require sequence identifiers is withdrawn in view of the sequence listing and amendment to the brief description of the drawings for Figs. 1-3 and 7-10 filed 9/28/2006.

7. The objection to the Brief Description of the Drawings for Figure 10 because it does not describe parts (A) and (B) as shown in Figure 10 is withdrawn in view of the amendment to the specification filed 9/28/2006.

8. The objection to the title of the invention as not descriptive of the claimed invention is withdrawn in view of the amendment filed 9/28/2006.

9. The rejection of claims 41-45 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation "derived" is withdrawn in view of the amendments to the claims.

10. The rejection of claim 45 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation "wherein the parent amino acids replace corresponding amino acids in the patching FR, wherein the patching FR is the FR derived from a different source used for patching, or that replaces the original FR of, the parent immunoglobulin." is withdrawn in view of the amendments to the claim.

11. The rejection of claims 41-44 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation "prior experience" is withdrawn in view of the amendments to the claims.

12. The rejection of claims 40-49 under 35 U.S.C. 103(a) as being unpatentable over Queen et al (US Patent 5,693,762, issues 12/2/1997, IDS filed 6/27/2001) in view of Cohen et al (U.S. Patent 5,908,925, issued 6/1/1999) and Benhar et al (Proc. Natl. Acad. Sci. USA, 91(25):12051-12055, December 6, 1994) is withdrawn in view of applicants arguments.

Objections/Rejections Maintained.

13. The objection to the specification in the use of the trademark Rituxan® is maintained.

The examiner acknowledges applicants' amendment replacing the second full paragraph at pg. 11, which amends the term "Rituxan" with the term "Rituximab". This has been fully considered but is not found persuasive. It is reiterated that the trademark should be capitalized wherever it appears and be accompanied by the generic terminology. Capitalizing the term "Rituximab" would overcome this rejection.

14. The provisional rejection of claims 40-49 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/482,759 is maintained.

The response filed 9/28/2006 states that applicant will consider filing a terminal disclaimer on a later date to overcome the rejection. This has been fully considered but is not found persuasive. In view that no terminal disclaimer has been filed and the claims have not been amended to overcome the present obviousness-type double patenting rejection, the rejection is maintained for reasons of record.

New Grounds of Objections/Rejections

15. Claims 41-44 and 46-49 are objected to in the recitation "A re-engineered... in view of the amendment to claim 40, which deleted the term "re-engineered". It is suggested that claims 41-44 and 46-49 be amended to delete the term "re-engineered" for consistency and readability of the claims.

Appropriate correction is required.

16. Claim 40 recites the limitation "the parent immunoglobulin". There is insufficient antecedent basis for this limitation in the claim. There is no recitation of a parent immunoglobulin in claim 40 prior to the recitation "the parent immunoglobulin" on line 20 of the claim and it is unclear what parent immunoglobulin is being referenced by the phrase. Amending claim 40 to recite "A framework (FR)-patched immunoglobulin containing heavy and light chain variable region sequences from a parent antibody", which was deleted in the amendment filed 9/28/2006, would overcome this rejection.

17. Claim 45 recites the limitation "said donor immunoglobulin sequences". There is insufficient antecedent basis for this limitation in the claim. It is unclear what donor immunoglobulin sequences are being referenced in the claim.

18. Claims 40-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Upon further consideration the presently recited proviso that not all of the replaced FR1, FR2 and FR3 of a FR-patched immunoglobulin heavy chain are from the same framework of a single immunoglobulin heavy chain and not all the replaced FR1, FR2 and FR3 of a FR-patched immunoglobulin light chain are from the same framework of a single immunoglobulin light chain constitutes new matter. This limitation appears to have been introduced in newly submitted claim 26 filed 6/28/2004. The specification

discloses FR-patched immunoglobulins wherein each of the FR's are dealt with separately (i.e., compartmentalized) and are patched with FR's from one or more human or primate immunoglobulins. Further, the specification discloses "When two or more FR's of the parent immunoglobulin chain are to be replaced, they can be patched with corresponding FR's either from the same human or primate immunoglobulin, or from different human or primate immunoglobulin within the same subgroup or in different subgroups, or from a combination of human and primate immunoglobulins." (as filed specification at pg. 9, lines 18-22). Thus, while the specification adequately discloses the replacement or patching of each FR of the heavy and light chain variable regions of a parental antibody with the corresponding framework sequences from different human antibodies, there is insufficient guidance and direction to the features currently claimed, i.e., wherein not all the replaced FR1, FR2 and FR3 of both the heavy and light chain of the FR-patched immunoglobulin are from a single immunoglobulin heavy and light chain, respectively. Applicant's reliance on a generic disclosure and possibly a single or limited species disclosed in the working examples of the as filed specification does not provide sufficient written support for the presently claimed subgenus of FR-patched immunoglobulins in which not all the replaced FR1, FR2 and FR3 of both the heavy and light chain of the FR-patched immunoglobulin are from a single immunoglobulin heavy and light chain, respectively. It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679,

683 (CCPA 1972) and MPEP 2163.05. Further, the examiner notes that the limitation in which not all the replaced FR1, FR2 and FR3 of both the heavy and light chain of the FR-patched immunoglobulin are from a single immunoglobulin heavy and light chain, respectively, was added subsequent to the applied prior art of Ohmoto et al (Molecular Immunology 32:407-416, 1995, cited on PTO-892 mailed 3/24/2004), which teaches a humanized antibody wherein the VH comprises FR4 from the ND human antibody and FR1-3 are from the EU human antibody.

In addition there is insufficient written support for the limitation wherein the framework sequences are replaced by the corresponding framework sequences from a different immunoglobulin of the same species (recitation in claim 40 as presently amended). As previously presented the claim 40 recited that the framework sequences defined as FR1, FR2, FR3 and FR4 are replaced or patched from the corresponding framework sequences from a different species and wherein the FR sequences from the different species could be from different immunoglobulins of the same species (e.g., each FR from a different human antibody) or from different immunoglobulins of different species. Thus, as previously presented the claims encompassed replacing each FR of the parent antibody with the corresponding framework sequences from a different species, however, as currently amended the claims now encompass replacing each FR of the antibody to be patched with framework sequences from a different immunoglobulin of the same species. For example, the claims are now drawn to a mouse antibody (i.e., a parent antibody) in which each FR is replaced with framework sequences from different mouse antibodies, or to a human parental antibody (i.e., a

parent antibody) in which each FR is replaced with framework sequences from different human antibodies. The specification only discloses FR-patching in the context of antibody humanization in which a non-human antibody (i.e., mouse antibody) is rendered less immunogenic in a human patient by replacing or patching each FR with a corresponding framework sequence from a human antibody or human antibodies, i.e., only from a different species. Applicants' response did not point out where support for presently amended claim 40 could be found in the originally filed disclosure. Although the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP 714.02 and 2163.06 ("Applicant should therefore specifically point out the support for any amendments made to the disclosure.").

Instant claims 40-49 now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in the present claims in the specification or claims, as-filed, or remove these limitations from the claims in response to this Office Action.

Conclusion

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827